Digital Mental Health 101: What Clinicians Need to Know When Getting Started

This guide is an introduction to the broad considerations that should be understood by mental health professionals and patients alike when engaging with mobile health (mHealth) solutions.

Part 3. What's Next: The Future of mHealth Ethics, Coverage, and Practice

Ethical and Legal Considerations

Nota bene: This section is not intended to provide legal advice. Please contact your malpractice carrier for specific legal questions.

As any treatment involves some examination of risks and benefits, so, too, does the use of apps in mental health care. These include concerns around the mobile health app use itself, how to effectively use these apps in the treatment process, and any considerations unique to providing mental health care.

A. Ethical Concerns and Patient Privacy

Of particular concern from an ethical perspective in using apps with patients is the degree to which the app adheres to expectations of the patient's privacy and confidentiality. A 2021 *Consumer Reports* guide suggested that even apps that appear at the top of app store searches do not offer complete or adequate privacy. This finding is supported by recent research studies highlighting that the majority of mHealth apps, mental health or not, suffer from privacy flaws. The health care professional and the patient should review the app's privacy policy to determine how it is using patient information (storing/transmitting) to ensure that it meets the expectations of both.

B. Harms, Risks, and Benefits

When evaluating apps, it is important to consider the amount of harm or risk versus benefit to the patient. This requires a personal analysis and highlights why it is important to evaluate apps in the context of the user at hand rather than apply a static rating score. What benefits could be expected from using this app? What evidence has been gathered for the benefits, and what are the possible harms of use? As noted above, one of the most common harms associated with use of any app in general is a breach of privacy or confidentiality and transmission of data to third parties. A more subtle

harm is a waste of time or the potential delay of more-effective treatments. When thinking of recommending an app, it is also important to assess the user's access to technology and their digital literacy. It can also be helpful to inquire about any current or past mHealth app use. This can be approached during visits in the same way one may inquire about herbal supplements or alternative treatments.

C. Patient Autonomy, Patient Consent, Liability, and Use of mHealth

A patient has the discretion to decide whether they want to use an app as a part of their treatment plan. Health care professionals should discuss with them the possible risks and benefits of any recommended therapy. Patients should not be coerced into using an app if they do not wish to use it. It is recommended that health care professionals incorporate an informed consent process stating the potential risk of loss of personal privacy and other risks when using apps.

Patients may assume that an mHealth app would adhere to the same privacy standards as health care entities, but this is often not the case, and it is important to share this difference with patients. Consent to use mHealth apps should be informed and voluntary. A patient's decision to use an app should be a genuine reflection of their autonomous choice. Many apps are not transparent in their methods of data collection, use, and sharing. Clinicians can play a vital role in educating patients on the risks and benefits of mHealth apps.

Liability, like informed consent for the use of technology, can also be addressed by the APA's ethics document: "Before they embark on innovative technology usage in practice, we advise that clinicians consider the potential liability connected with such usage and engage in an informed consent process with the patient, including disclosure of any financial interest the psychiatrist may have in the app. The app is an aid to the overall care delivery for the patient and not a replacement of the interactions with the provider. There is also some potential for boundary crossings or violations when the therapeutic relationship steps outside the confinements of a traditional setting."

Health apps in general have areas of relevance in health care law, such as medical malpractice and personal privacy. Private health apps are also subject to product liability laws. However, existing laws are not necessarily suited to the unique aspects of health apps. The Office for Civil Rights of the Department of Health and Human Services (HHS), the Federal Trade Commission (HHS), and the Food and Drug Administration (FDA) have been the most involved in regulating health apps. HHS plays a major role in monitoring HIPAA violations, while the FTC has the capacity to regulate false and deceptive advertising and has acted against several apps making false health claims. It has also expressed "the sensitive nature of health information and noted that lack of attention to privacy could lead to an erosion of trust in the mobile marketplace," and in 2021 the FTC noted it would enforce the HIPAA breach rules even for wellness apps that do not typically fall under HIPAA. For a complete discussion of guidance offered by the FDA on mobile medical apps, as well as an explanation of HIPAA adherence in using mHealth, please refer to Section I of this document.

Given the absence of the aforementioned—and other—formal governing bodies' oversight of the development and use of apps, some sources have taken a stance that the responsibility for ethical use rests solely on the licensed clinician and that it is advisable to include information related to mHealth apps in informed consent. Developers of private mHealth apps may be subject to available product liability claims that are related to design defects, breach of warranty, or a failure to warn.

D. Other Legal and Ethical Considerations

The Computer Fraud and Abuse Act of 1986 prevents unauthorized access of data from a person's computer. The Electronic Communications Privacy Act of 1986 bars unauthorized interception of communications and accessing of stored communications with the exception of user consent. User consent allows apps to bypass this act and transmit data to third parties. The issue is that many privacy policies could be considered ungenuine reflections of autonomous choice, where they are not written in plain language to explain practices that highly affect users such as data collection, storage methods, risk of data leak to the public, unexpected consequences of data leaks or transmission, potential of data use for research, data ownership, access, profit agreements, and options to quit or remove data after collection starts. Each person has the right to decide how risk-averse to be, and many software agreements and app use agreements are not sufficiently clear and transparent to enable this decision-making.

As many mHealth apps do not have an evidence base supporting their use, it is important for clinicians who are considering using apps in clinical care to evaluate the app themselves before recommending it to a patient. Children and adolescents are most likely to gravitate toward mHealth app use given preferences toward digital communication, convenience, accessibility, discretion, and low cost of these services; however, some developers may take advantage of this vulnerable population. Vetting an app prior to use can be helpful. The way an mHealth app incorporates safety is also important: Does the app tell patients to seek professional help in case of an emergency or suicidal ideation? Does the app provide a working suicide crisis line number? Does the app have a disclaimer stating that this app is meant to complement not replace professional health care? Apps that do not include these disclaimers are at increased risk of jeopardizing a patient's safety.

When introducing an app to a patient, it is recommended that the app be used in conjunction with traditional care. For instance, if the app is used to improve safety, the clinician should complete their own safety assessment and create a safety plan with the patient. Then, the app may be incorporated as additional support, not to replace treatment.

When in doubt, core medical ethical principles of beneficence, nonmaleficence, justice, and autonomy can be used to guide decision-making. Apps can enable vast data collection, especially those using digital phenotyping, and consideration for use of the data to benefit care outcomes must be weighed against risks. Capturing data for the sake of data capture will likely not be supported when considering the ethical principle of beneficence. Using apps to augment care but not to replace evidence-based care is well-aligned with the ethical principle of nonmaleficence and even current FDA approvals, which are

only for apps to augment ongoing clinician-directed care. Assessing digital literacy and ensuring equal access aligns with justice and autonomy.

Finally, with respect to informed consent, there are a number of factors that a clinician should consider and discuss fully with patients in an informed consent process prior to use of a mental health app in treatment. While this document will not enumerate those in detail, these considerations are identified in Opinion N.32 of the APA Ethics Committee, which is available within the Opinions document.

Payment Models, Billing, and Coverage

Many payers, including federal (Medicare), state (Medicaid), and private insurance companies are investing in a transition in payment models from "volume" to "value." This topic remains under active consideration and in flux at the time of this report. As a part of incentives for providers to make this transition, payers are beginning to adopt reimbursement models that include the use of technology in reimbursement and may reflect any improvements in health outcomes that arise from the incorporation of technology into care. Since the passing of the HITECH (Health Information Technology for Economic and Clinical Health) Act in 2009, health care professionals and hospitals have been incentivized to adopt various technologies into care, including electronic health records, electronic prescribing, and more.

Moreover, this move to adopt technology was further integrated into payment models with the passage of additional legislation via the Medicare Access and CHIP Reauthorization (MACRA) Act of 2015 by providing incentives for health care providers to adopt alternative payment models (APMs), featuring the use of technology in reimbursement calculations.

However, there are still only a limited number of use cases where various mHealth solutions are specifically enumerated in medical coding for reimbursement via Current Procedural Terminology (CPT®). While some remote patient monitoring (RPM) codes have been in place for some time for the purposes of monitoring patient physiologic symptoms (e.g., portable EKG, and other sensor technology), the specific application of CPT for mobile apps remains in development by the American Medical Association (AMA). New proposals such as draft federal mental health legislation and various local and state efforts suggest that there is interest in soon beginning to reimburse clinicians for the incorporation of apps into care delivery. With broad changes in regulations around telehealth, it is likely there will be rapid progress in this area.

A. Future Possibilities for Digital Health Payment Models

In development at the AMA are "Category III" CPT codes that seek to address how mHealth technologies might be reimbursed in future CPT publications. Category III codes are those which are created to track the utilization of emerging technologies, services, and procedures. In the future, these might be used to set reimbursement policy for the use of certain apps. Also, it remains to be seen whether current RPM codes might be used for monitoring symptoms or physiologic states specific for mental health. As new

technologies emerge that are capable of connecting to a mobile device and capturing data via an app, CPT codes designed to set reimbursement rates for such use may evolve.

Future Directions & Other Applications for This Work

While this resource package offers a snapshot of the current digital mental health landscape, the field is evolving rapidly, bringing with it possibilities and caveats. For instance, while the use of digital health tools has the potential to complement traditional clinical intervention, evidence about the efficacy and appropriate application of these tools is still emerging. Moreover, the use of these tools is currently limited to those who have access to the technology and who can use it consistently and effectively (see the explanation of "digital literacy" and the "digital divide"). To that end, institutions such as the American Psychiatric Association must assume responsibility for continuing advocacy work on behalf of stakeholders to a) raise awareness of digital health treatments, b) promote research in digital mental health, and c) engage in robust dialogue with stakeholders around payment models for these adjunct treatments.

As technology continues to advance, we must ensure that each health profession is appropriately prepared to incorporate these advancements into practice. This means that education preparation programs need to incorporate the use of technology into curricular content. We all must be able to describe, use, incorporate into delivery of care, communicate about, and adhere to ethical and organizational policies around information and communication technologies. To achieve these competency expectations, health care professions and organizations must provide learning opportunities in addition to staying apprised of the ever-changing environment of technology. While this is not an easy task, if we keep the basic principles of high-quality care in mind, we can judge developments and continue to harness technology to benefit our patients.

Appendix A: About the Authors and APA App Advisor

The American Psychiatric Association's App Advisor is an initiative begun in 2019 that builds on the organization's work in app evaluation that began in 2014. Its purpose is to develop guidance and resources around the use of mHealth in mental health care, targeting clinicians, patients, policymakers, and the general public. The group is comprised of an array of mental health clinicians, professionals with expertise in health information technology, and those with lived experience of mental illness.

This group was assembled through an open call for nominations and submissions issued to the general public in June 2019. Following a review and selection process undertaken by APA's Committee on Mental Health Information Technology, the group first convened in December 2019 in Washington, D.C., at the APA's headquarters. At this first meeting, the panel reviewed and revised APA's App Evaluation Model—a framework offering guidance on reviewing and selecting mental health apps in clinical care. Through consensus building, the panel revised this model to the iteration available on the APA's website today.

As a natural outgrowth to its work in app evaluation, the panel is now focused on developing guidance focused on the use of mHealth in mental health care.

Appendix B: Key Terms

A selection of key terms from this document and in the digital mental health environment include:

Applications (apps): Computer program or software application, primarily designed to run on mobile devices including smartphones or tablets.

Digital inclusion: Supporting people to achieve knowledge, confidence, and skills to engage with digital health services across a variety of media and platforms.

Digital literacy: Cognitive, technical, and physical access to and comfort with communications technology to find, use, and share information.

Digital therapeutics (DTx): An umbrella term that describes treatments or therapies that use technology to deliver behavioral treatments that support changes in patient behavior.

Mobile Health (mHealth): Patient-driven mobile health support and self-management tools.

Prescription digital therapeutics (PDT): Software-based therapies designed to evaluate or treat a medical condition and are prescribed by a provider.

Remote patient monitoring (RPM): Non-face-to-face monitoring of primarily physiologic factors to understand a patient's health status.

Telehealth: Care that is delivered using technology and without an in-person interaction, including through video chat, secure messaging and file exchange, internet-capable devices, or phone.

Virtual reality (VR): A computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way.

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